REMARKS

Initially, it is noted that the Examiner has indicated that claim 26 has been allowed and that claim 24 contains allowable subject matter. It is noted that claim 24 depends from claim 26 and further defines a microfluidic device not shown or suggested in the art. It is believed that claim 24 is allowable as depending from the allowable base claim and in view of the subject matter of the claim.

The Examiner has objected to the drawings under 37 C.F.R. §1.83(a) and has rejected claims 21 and 27 under 35 U.S.C. §112, first paragraph, because the Examiner believes the limitation:

> a conduit having an input communicating with the aqueous solution and an output, the conduit having a first configuration wherein the aqueous solution is isolated from the chamber and a second configuration wherein the chamber communicates with the aqueous solution through the conduit;

in claim 21 and the similar limitation in claim 27 are not disclosed in the Specification and constitute new matter. As such, Applicant has cancelled this limitation from claims 21 and 27. Consequently, withdrawal of the Examiner's objection to the drawings under 37 C.F.R. §1.83(a) and rejection of claims 21 and 27 under 35 U.S.C. §112, first paragraph, is respectfully requested. In addition, the Examiner has rejected claim 27 under 35 U.S.C. §112, second paragraph, due to a typographical error. Applicant has corrected the typographical error in claim 27 pointed out by the Examiner and withdrawal of the Examiner's rejection of claim 27 under 35 U.S.C. §112, second paragraph, is respectfully rejection.

The Examiner has rejected claims 21 and 27-28 for a variety of reasons. More specifically, the Examiner has rejected claims 21 under 35 U.S.C. § 102(e) as being anticipated by Ziaie et al., U.S. Patent Application No. 2004/0248326. In addition, the Examiner has rejected claims 21 and 27-28 under 35 U.S.C. § 103(a) as being unpatentable

over Kriesel et al., U. S. Patent No. 6,416,495 in view of Kriesel et al. U.S. 5,693,018. Finally, claims 21 and 27-28 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Eckenhoff et al. U.S. Patent No. 4,552,561 in view of the Ziaie et al., '326 application. As hereinafter described, applicant has amended independent claims 21 and 27 to more particularly define the invention for which protection is sought. Favorable consideration of claims 21 and 27-28 is respectfully sought in view of the following comments.

Claim 21 defines a microfluidic device for delivering a drug to an individual. The device includes a body defining a chamber and including a membrane for defining a reservoir. The membrane isolates the reservoir from the chamber. An output needle has an input in communication with the reservoir and an output receivable within the individual. An aqueous solution is injectable into the chamber of the body. An adhesive is provided for affixing the body to the individual. A pressure source including a hydrogel member is received within the chamber. The hydrogel member is expandable in response to exposure to the aqueous solution injected into the chamber. The hydrogel member is engageable with the reservoir and urges the drug from the reservoir through the output needle as the hydrogel member expands. A valve interconnects the reservoir and the output needle. The valve is movable between a non-actuated position wherein the valve prevents the flow of the drug from the reservoir to the output needle and an actuated position wherein the valve allows for the flow of the drug from the reservoir to the output needle. As hereinafter described, none of the cited references show or suggest a microfluidic device for delivering a drug to an individual that incorporates an aqueous solution that is *injectable* into the chamber of the body wherein a hydrogel member expands in response to exposure to the aqueous solution *injected* into the chamber.

The '326 application discloses a plurality of hydrogel actuated devices that are used for controlled drug delivery either in response to a predetermined stimulus or for pulsating delivery. It is noted, however, that the device is implantable such that actuation of the

hydrogel is accomplished by diffusion of the aqueous solution thorough a porous membrane. There is no suggestion or teaching in the '326 application to provide a microfluidic device for delivering drugs that incorporates an aqueous solution that is *injectable* into the chamber of the body wherein a hydrogel member expands in response to exposure to the aqueous solution *injected* into the chamber. Clearly, since the aqueous solution passes through a porous membrane, there would be no incentive or purpose to modify the device disclosed in the '326 application to provide for injection of an aqueous solution into a chamber housing the hydrogel.

The Kriesel et al. '495 patent discloses an implantable fluid delivery apparatus for infusing medical fluids into a patient. The apparatus includes a bolus delivery system including a magnetically responsive polymer gel which, upon being stimulated by an electro-magnet, delivers precise bolus doses of medicinal fluids to a patient. It is noted that the apparatus disclosed in the '495 patent is implantable. Hence, it is contemplated for the polymer gel to be responsive to a singular external stimuli, e.g., magnetic stimulus or electro-magnetic waves. This structure differs substantially from the microfluidic device defined in independent claim 21. More specifically, claim 21 requires the microfluidic device to include an aqueous solution that is *injectable* into the chamber of the body wherein a hydrogel member expands in response to exposure to the aqueous solution *injected* into the chamber. Nothing in the method in the '495 patent shows or suggests such a structure. Further, modifying the apparatus disclosed in the '495 patent to provide a microfluidic device incorporating such a conduit would require significant modification to the prior art device, as well as, significant experimentation. As hereinafter described, the subdermal delivery device disclosed in the '018 patent cannot cure the deficiencies of the Kriesel et al. '495 patent.

The Kriesel et al. '018 patent is directed to a subdermal delivery device that includes a needle and an adhesive for affixing the device to an individual. Nothing in the '018 patent shows or suggests a hydrogel pressure source responsive to a predetermined parameter of an aqueous solution. Further, nothing in the '018 patent shows or suggest the hydrogel pressure

source being housed in a chamber or an aqueous solution being injectable into the chamber in which the hydrogel member resides such that the hydrogel member expands in response to exposure to the aqueous solution *injected* into the chamber. Hence, the combination suggested by the Examiner does not teach the microfluidic device of claim 21.

Finally, the Eckenhoff et al. '561 patent discloses a self-contained body mounted pump assembly for continuously administering a therapeutic agent. The pump has a transparent top through which the contents can be seen. The pump assembly is driven by a fluid imbibing, preferably osmotic pump, and contains its own source of actuating fluid (namely, hydrogel 18). The liquid component of hydrogel 18 diffuses through wall 16 and dissolves the osmagent 15 in pump 11. The saturated solution formed within pump 11 is emitted steadily through outlet 17 to cause displacement partition 10 to be steadily forced into chamber 25 and displace the contents thereof. As the Examiner points out, the hydrogel may be stored in a tube prior to being deposited in the pump assembly. However, nothing in the '561 patent suggests microfluidic device incorporating a separate aqueous solution that is injectable into a chamber thereof wherein a hydrogel member in the chamber expands in response to exposure to the aqueous solution *injected* into the chamber. In the '561 patent, no aqueous solution is provided that is injectable into a chamber housing a hydrogel member (the pressure source), as required by claim 21. Further, the hydrogel member in the '561 patent does not expand in response to the aqueous solution injected into the chamber, as required by independent claim 21. Finally, since the liquid component of hydrogel 18 diffuses through a permeable wall 16 and dissolves the osmagent 15 in pump 11, there would be no incentive or purpose to modify the pump assembly disclosed in the '561 patent to provide for injection of an aqueous solution into the osmagent. Further, as noted above, the '326 application cannot cure the deficiencies of the '561 patent since there is no suggestion or teaching in the '326 application to provide a microfluidic device for delivering drugs that incorporates an aqueous solution that is *injectable* into the chamber of the body wherein a hydrogel member expands in response to exposure to the aqueous solution *injected* into the chamber.

In view of the foregoing, it is believed that independent claim 21 defines over the cited references and is in proper form for allowance.

Claim 27 defines a microfluidic device for delivering a drug to an individual. The microfluidic device includes a body defining a chamber for receiving an aqueous solution therein and including a membrane for defining a reservoir. The membrane isolates the reservoir from the chamber. An output needle has an input in communication with the reservoir and an output receivable within the individual. A predetermined physical property is injectable into the chamber of the body. An adhesive is provided for affixing the body to the individual. A pressure source including a hydrogel member is received in the chamber and is expandable in response to exposure to the predetermined physical property injected into the chamber. The hydrogel member engages the reservoir and urges the drug from the reservoir through the output needle as the hydrogel member expands. A valve interconnects the reservoir and the output needle. The valve is movable between a non-actuated position when the valve prevents the flow of drug from the reservoir to the output needle and an actuated position when the valve allows for the flow of the drug to the reservoir to the output needle.

Similar to claim 21, claim 27 has been amended to specify that the microfluidic device includes a microfluidic device for delivering a drug to an individual that incorporates a predetermined physical property that is *injectable* into the chamber of the body wherein a hydrogel member expands in response to exposure to the predetermined physical property *injected* into the chamber. As heretofore described, nothing in any of the cited references shows or suggests such a structure. In fact, such an arrangement is entirely absent from all of the cited references. Consequently, it is believed that independent claim 27 defines over the cited references and is in proper form for allowance.

Claim 28 depends from claim 27 and further defines a microfluidic device not shown or suggested in the cited references. More specifically, claim 28 specifies that the predetermined physical property is defined by an aqueous solution. Again, such a structure is not disclosed in the cited references. As such, it is believed that claim 28 is allowable as depending from an allowable base claim and in view of the subject matter of the claim.

In view of the foregoing, applicant believes that the present application with claims 21, 24 and 26-28 is in proper form for allowance and such action is earnestly solicited. The Director is hereby authorized to charge payment of any other fees associated with this communication or credit any overpayment to Deposit Account No. 50-1170.

Respectfully submitted,

Dated: 1/26, 2009

By: _____
Peter C. Stomma
Registration No. 36,020

Boyle Fredrickson S.C.
840 North Plankinton Avenue
Milwaukee, WI 53203
Phone: 414.225-9755
Fax: 414.225.9753
Attorney Docket No.: 282.033